REMARKS

Rejection of claims 66-82 under 35 U.S.C. § 102(e) as being anticipated by Ebner, *et al.*, U.S. 2003/0003545

In the June 4, 2003 Office Action, claims 66-82 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ebner, *et al.*, U.S. 2003/0003545 ("Ebner, *et al.*"). The Examiner maintains that Ebner, *et al.*, "disclose a polynucleotide of IL-21, which has the same amino acid sequence of SEQ ID NO:29, and is identical to SEQ ID NO:3 of the present invention." *See* page 2 of Office Action dated June 4, 2003, incorporating views expressed on pages 2 and 3 of Office Action dated February 24, 2003. The Examiner further asserts that Ebner, *et al.* teaches a pharmaceutical composition comprising the polypeptide and a kit comprising the composition and therefore, anticipates claims 66-80. *See p*age 3 of the Office Action dated February 24, 2003. The Examiner also notes that the functional limitations of the claims are "either an inherent property of the same composition, or an intended use of the claimed composition, and do not alter the nature of the claimed composition." Finally, the examiner rejected claims 81 and 82 under 35 U.S.C. § 102(e) based on Ebner's disclosure of a fusion protein comprising said polypeptide fused to antibody domains such as an antibody Fc region. *See* page 3 of the February 24, 2003 Office Action.

The Examiner maintains that Ebner *et al.*, is prior art under §102(e) due to the existence of claims under 35 U.S.C. §119(e) in the Ebner *et al.*, application, to certain earlier-filed provisional applications. In particular, the Examiner observes that Ebner, *et al.*, claims priority under 35 U.S.C. §119(e) to three provisional applications, No. 60/087,340, filed May 29, 1998; No. 60/099,805, filed Sept. 10, 1998; and No. 60/131,965, filed April 30, 1999. *See* page 2 of June 4, 2003 Office Action.

Applicant respectfully traverses this rejection.

As an initial point, Applicant notes that the first of the three provisional applications to which claims of priority are made under 35 U.S.C. § 119(e) in Ebner, *et al.* does not, in fact, disclose the polypeptide sequence cited by the Examiner (i.e., SEQ. ID No. 29). The sequence labeled as SEQ ID NO: 29 of Ebner *et al.*, first appeared in the provisional application filed by Ebner *et al.*, on September 10, 1998; namely, provisional application no. 60/099,805 (the '805 application). As such, the Ebner, *et al.* disclosure cannot be given a prior art effective date

under § 102(e) for the recited sequences (SEQ ID NOS: 29) as of the first-claimed filing date of the '340 application (i.e., May 29, 1998).

Applicant notes that it is well-settled law that a patent (and, by implication, a patent application published pursuant to 35 U.S.C. 122(b)) shall have effect under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter in question. If the patent or published application claims the benefit under 35 U.S.C. § 120 (and by implication under 35 U.S.C. § 119(e)) to an earlier filed application, that patent or published application shall not be entitled to prior art effect under § 102(e) if the earlier filed application does not provide a sufficient disclosure under 35 U.S.C. § 112, first paragraph for the subject matter in question. To be given effect under § 102(e), the claims of the reference patent must be supported in the manner required by 35 U.S.C. § 112 in the priority application whose date is relied on to establish the prior art status of the patent. *See In re Wertheim*, 646 F2d 527, 209 USPQ 554 (CCPA 1981); and MPEP 2136.03, sub-heading IV.

Applicant also directs the attention of the Examiner to the declaration submitted pursuant to 37 CFR § 1.131, executed by the inventors of the present application, and provided herewith. Applicant submits that the declaration effectively antedates Ebner, *et al.* particularly in view of the observations provided above which establish that Ebner, *et al.* is not entitled to a prior art date pursuant to 35 U.S.C. 102(e) of May 29, 1998 (i.e., the filing date of the '340 application).

Accordingly, Applicants submit that Ebner, *et al.* is not prior art to the presented claims under § 102(e) and as such, cannot be relied upon to support a § 102(e) rejection of said claims. *See* MPEP § 2136.05. Applicant respectfully request the Examiner to withdraw the rejection of claims 61-63 and 68-72 under § 102(e) rejection based on Ebner, *et al.*

Rejection of Claims 66-68 and 71-80 under 35 U.S.C. § 102(e) as being anticipated by Gorman, *et al.*, US Patent No. 6,562, 578 B1

In the June 4, 2003 Office Action, claims 66-68 and 71-80 are rejected under § 102(e) as being anticipated by Gorman, *et al.*, US Patent No. 6,562, 578 B1 ("Gorman, *et al.*"). The Examiner maintains that Gorman, *et al.*, disclose a polypeptide sequence, Seq. ID NO. 23, that has 100% sequence identity to SEQ ID NO:3 of the present invention. The examiner states that a signal sequence of 17 amino acids is indicated in Gorman's SEQ ID NO:23 (-17 to –1), which

suggests that the mature polypeptide lacks the signal peptide. The Examiner further maintains that

> "while Gorman et al., does not explicitly teach a composition of the polypeptide and a pharmaceutically acceptable carrier, it is well known in the art that a purified protein is usually used in combination with other agent(s) and can not be (rather than) used as its crystal form alone. Dissolving solutions, such as water, buffers or media, meet the limitation of being a pharmaceutically acceptable carrier."

Upon this basis the Examiner maintains that one of ordinary skill in the art would consider Gorman, *et al.* in possession of such a composition. Therefore, Gorman, *et al.* anticipates claims 66-68 of the instant application.

Applicant respectfully traverses this rejection.

Gorman, *et al.* was filed on January 10, 2000, and makes a claim under 35 U.S.C. 119(e) to U.S. provisional application no. 60/115,506 (the '506 application), filed on January 11, 1999. The '506 application, however, does not disclose the polypeptide sequence labeled as SEQ ID NO: 23 in Gorman, *et al.* No other sequence bearing the recited homology to the presently claimed polypeptide sequence is disclosed in the '506 application. Accordingly, Gorman, *et al.* is not entitled to have a prior art effect under §102(e) for the polypeptide sequence labeled as SEQ ID NO: 23 prior to the actual filing date of the Gorman, *et al.* application that resulted in the patent (i.e., January 10, 2000).

Applicant further notes that the effective filing date of the present application is prior to January 10, 2000 by operation of 35 U.S.C. §§ 119 and 120. As such, Gorman, *et al.*, is not prior art to the presented claims under 35 U.S.C. § 102(e).

Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of claims 66-68 and 71-80 under 35 U.S.C. § 102(e) based on Gorman, *et al.*

Rejection of claims 69 and 70 under 35 U.S.C. § 103(a) as obvious over Gorman, *et al.* and rejection of claims 81 and 82 under 35 U.S.C. § 103(a) as obvious over Gorman, *et al.* in view of Capon, *et al.*, U.S. Patent No. 5,116,964.

In the June 4, 2003 Office Action, claims 69 and 70 are rejected under § 103(a), as obvious over Gorman, *et al.* In the Office Action, the Examiner states that while Gorman, *et al.* does not explicitly teach an article containing a composition of the polypeptide, it would have been obvious to one or ordinary skill in the art to "make an article containing said composition and instructions for the purpose of research and/or clinical applications, such as immunoassays or binding assays, because such an article would facilitate the applications, and commercial distribution." *See* page 4 of the June 4, 2003 Office Action.

In addition, claims 81 and 82 are rejected over Gorman, *et al.* in view of Capon, *et al.* The Examiner acknowledges that Gorman, *et al.* does not teach a fusion protein of the claimed polypeptide. However, the Examiner asserts that Capon, *et al.* discloses a novel polypeptide comprising an immunoglobulin Fc region and a target protein sequence for use, among other things, to extend the *in vivo* half-life of the resulting fusion protein. Accordingly, the Examiner finds that one of ordinary skill in the art would have been motivated to use the polypeptide disclosed in Gorman, *et al.* to make a fusion protein as taught by Capon in order to, for example, facilitate protein purification.

Applicant respectfully traverses these rejections.

First, for the reasons presented above in relation to the rejection of claims 66-68 and 71-80 over Gorman, *et al.*, Applicant maintains that Gorman, *et al.*, is not prior art under 35 U.S.C. § 102(e) to the present application. As such, Applicants respectfully request the Examiner withdraw the rejection of claims 69, 70, 81 and 82 under § 103 based on Gorman, *et al.*

With respect to the rejection of claims 81 and 82 over Gorman, *et al.* in view of Capon, *et al.* Applicant points out that the combined teachings of those references would not have motivated one of ordinary skill in the art to make a fusion construct, as described in Capon *et al.*, from the protein disclosed in Gorman, *et al.* Capon, *et al.* discloses novel polypeptides comprising a "ligand binding partner" fused to a stable plasma protein. Capon *et al.* Col 5, lines 14-15. Capon, *et al.* defines "ligand binding partner" as "proteins known to function to bind specifically to target ligand molecules...." Capon *et al.* Col 7, lines 13-15. The definition of "ligand binding partner" in Capon *et al.*, therefore, encompasses proteins that bind other molecule, not proteins that are bound by another molecule. The protein of the current invention, being a cytokine, is a protein that is *bound* by a receptor rather than one that *binds* other proteins. Therefore, an ordinarily skilled artisan reading the disclosure of Capon *et al.* would not have been motivated to construct a fusion protein as taught by Capon, *et al.* (including a ligand

binding partner) using the protein described in the current invention (a ligand). The rejection to claims 81 and 82 based on the combination of Gorman, *et al.* and Capon, *et al.* should, therefore, be lifted.

Additional Comments

Applicants, for the convenience of the Examiner, have enclosed copies of the applications referred to in the declaration submitted pursuant to 37 CFR 1.131. Specifically, said copies are attached as exhibits to said declaration.

In view of this response, Applicant submits that the present application is in condition for allowance and should be passed to issue. If the Examiner believes that the application is not in condition for allowance or cannot be passed to issue in view of this response, Applicant respectfully requests that the Examiner contact the undersigned prior to taking any further action in this application.

Respectfully submitted,
for GENENTECH, INC.

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